I respectfully request the NCCN Breast Cancer panel to review the enclosed data for inclusion of the breast-specific gamma imaging (BSGI) procedure, also referred to as molecular breast imaging (MBI), in the diagnostic evaluation of breast carcinoma.

**Specific Changes:** Add, “BSGI may be used when the diagnosis is inconclusive after standard work-up with ultrasound and mammography or as an alternative to breast MRI when MRI is not available or is contraindicated in a specific patient.” To the following sections: MS-10, Additional workup for stage IIIA (T3, N1, M0) disease, MS-37: End of first sentence on page

**FDA Clearances:**
1. Pharmaceuticals: *Tc99m-Sestamibi* is indicated for planar breast imaging as a second line diagnostic drug after mammography to assist in the evaluation of breast lesions in patients with an abnormal mammogram or a palpable breast mass.
2. Detector Systems: *Dilon 6800 Series Gamma Camera(s), Gamma Medica LumaGem, General Electric*

**Rationale:** BSGI is a molecular breast imaging procedure capable of detecting breast malignancies that are either occult or underestimated by mammography and ultrasound and, like breast MRI, it has demonstrated the ability to improve patient management but in contrast, BSGI has no known contraindications for use and can therefore be utilized in situations where MRI is unavailable or in patients unable to undergo MRI.


5. Weigert J, Bertrand M, Stern L, Kieper D. Results of a Multicenter Patient Registry to Determine the Clinical Impact of Breast-Specific Gamma Imaging, a Molecular Breast Imaging


Sincerely,
Douglas Kieper